DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sintea Biotech, Inc.
% Ms. Danielle Wernikowski
Regulatory Affairs
407 Lincoln Road, 10L
Miami Beach, FL 33139

JUL 18 2008

Re: K081631
Trade/Device Name: Posterior Lumbar System Multi-Axial Screws - DESCO
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
~~Regulatory Class:~~ ~~II~~
Product Code: MNI, MNH, KWP
Dated: May 19, 2008
Received: June 18, 2008

Dear Ms. Wernikowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081631

Device Name: Posterior Lumbar System Multi-Axial Screws - DESCO

Indications for Use:

The Posterior Lumber System Multi-Axial Screw DESCO is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

The Posterior Lumbar System ~~is a pedicle screw system intended to provide~~ immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylothesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Posterior Lumbar System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to Sacrum) with removal of the implants after the attainment of a solid fusion.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Barbara Brewer for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081631

Sintea Biotech Posterior Lumbar System
Multi-Axial Screw - DESCO
510(k) Summary
May 19, 2008

I. Company: **Sintea Bioteqch, Inc.**
407 Lincoln Rd. Suite 10L
Miami Beach, FL 33139
(305) 673-6226

II. Proprietary Trade Name: Sintea Biotech Posterior Lumbar System Multi-Axial Screw - DESCO

Regulation Number: 888.3050, 888.3070

Regulation Name: Spinal Interlaminal Fixation Orthosis, Spondylolosthesis Spinal Fixation Device System, and Pedicle Screw Spinal System, Class II

Product Code: KWP, KWQ, MNI

III. Product Description

As a special 510(k) submission, the predicate device to which we are claiming equivalence is our own product, Sintea Biotech's Posterior Lumbar System (K020085). This 510(k) submission represents a modification to the predicate, in which the locking cap threads are modified and additional size diameter screws are added to the already cleared Posterior Lumbar System.

IV. Indications

The Posterior Lumber System Multi-Axial Screw DESCO is a posterior, nonpedicle screw system of the noncervical spine indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, tumor, pseudoarthrosis, and failed previous fusion.

The Posterior Lumbar System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylothesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The Posterior Lumbar System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to Sacrum) with removal of the implants after the attainment of a solid fusion.

V. Device Description

Please see 510(k) submission for Sintea Biotech's Multi-Axial Screws System, K043355.

VI. Performance Data

Please see 510(k) submission for the Sintea Biotech's Multi-Axial Screws System, K043355

VII. Substantial Equivalence

Sintea Biotech, Inc. believes that the additions to the Posterior Lumbar System Multi-Axial Screws are substantially equivalent to the Sintea Biotech's Multi-Axial Screws System (K043355) with respect to functional design, indications for use, and principles of operation, performance, and materials.